# INFORMED CONSENT: CONTROL GROUP

INTRODUCTION:
Good day, my name is Carin Dreijer, I am an Occupational Therapist at Chris Hani Baragwanath Hospital, Occupational Therapy Department. I would like to ask you to consider taking part in a research study, entitled: The effects of a comprehensive Occupational Therapy intervention programme on the Occupational Performance of patients with Rheumatoid arthritis, living in Soweto

Before agreeing to participate, it is important that you read and understand the following explanation of the purpose of the study, the study procedures, benefits, risks, discomforts, and precautions. This information is to help you to decide if you would like to participate. You should fully understand what is involved before you agree to take part in this study.

- If you have any questions, do not hesitate to ask me.
- You should not agree to take part unless you are satisfied about all the procedures involved.
- If you decide to take part in this study, you will be asked to sign this document to confirm that you understand the study. You will be given a copy to keep.

PURPOSE OF THE STUDY:

- You have been diagnosed as suffering from Rheumatoid Arthritis and I would like you to consider taking part in the research of a new programme that will aim to help you cope better with your arthritis at home.
- The purpose of this study is to determine how Occupational Therapy treatment in the hospital will help you cope better with your every day tasks.

LENGTH OF THE STUDY AND NUMBER OF PARTICIPANTS:

- Approximately 60 patients will participate in this study.
- The total amount of time required for your participation in this study will be a maximum of 1 week in hospital and 2 hours afterwards.
- You will be asked to visit me once more after your discharge.

PROCEDURES:
At each following visit you will be asked to fill in 2 questionnaires about how you are coping with every day tasks:

- 1 week admission to C H Sara Hospital
- Visit 2: 4 months later

BENEFITS OF THE STUDY:

- The potential benefit from your participation in this study may be that you will be able to cope better with your every day tasks at home, e.g. washing and cooking.
- However, you may not benefit from this study.

- Your participation in this study will contribute to medical knowledge that may help other patients that, like you, have RA and suffer with their daily tasks.

RIGHTS AS A PARTICIPANT IN THIS STUDY:

- Voluntary:

Your participation in this study is entirely voluntary and you can decline to participate, or stop at any time, without stating any reason. Your withdrawal will not affect your access to other rehabilitation services.

REIMBURSEMENT FOR STUDY PARTICIPATION:

- You will not be paid to participate in this study but your transport and, when necessary, refreshment costs will be reimbursed adequately.

ETHICAL APPROVAL:

- This study protocol has been submitted to the University of the Witwatersrand, Human Research Ethics Committee (HREC) and written approval has been granted by that committee.

SOURCE OF ADDITIONAL INFORMATION:

- For the duration of the study, you will be under the care of the rheumatology doctors as usual, but all OT treatment will be provided by myself. If at any time between your visits, you feel that you need to contact me, please do so. You can get hold of me at the C H Bara Hospital OT department: (011) 933 8294 / 933 9113

CONFIDENTIALITY:

- All information obtained during the course of this study, including hospital records, personal data and research data will be kept strictly confidential. Data that may be reported in scientific journals will not include any information that identifies you as a participant in this study.
- This information will be reviewed by authorised representatives of the hospital and University of the Witwatersrand.
- The information might also be inspected by the University of the Witwatersrand, Human Research Ethics Committee, as well as your personal doctor. Therefore, you hereby authorise me to release your medical records to the University of the Wtwatersrand, Human Research Ethics Committee (HREC).
- These records will be utilised by them only in connection with carrying out their obligations relating to this clinical study.
- Any information uncovered regarding your test results or state of health as a result of your participation in this study will be held in strict confidence. You will be informed of any finding of importance to your health or continued participation in this study but this information will not be disclosed to any third party in addition to the ones mentioned above without your written permission.

INFORMED CONSENT:

- I hereby confirm that I have been informed by Carin Dreijer (OT) about the nature, conduct, benefits and risks of clinical study.
- I have also received, read and understood the above written information (Patient Information and Informed Consent) regarding the clinical study.
- I am aware that the results of the study, including personal details regarding my sex, age, date of birth, initials and diagnosis will be anonymously processed into a study report.
- I may, at any stage, without prejudice, withdraw my consent and participation in the study.
- I have had sufficient opportunity to ask questions and (of my own free will) declare myself prepared to participate in the study.

**Patient:**

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Printed Name Signature or Thumbprint Date and Time

I, Carin Dreijer (OT), herewith confirm that the above patient has been fully informed about the nature, conduct and risks of the above study.

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Printed Name Signature Date and Time

Translator/ other person explaining Informed Consent (Designation):

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Printed Name Signature Date and Time